

REMARKS

STATUS OF THE CLAIMS

Claims 1-52 were originally pending and have been subject to restriction, as discussed below. Claim 30 has been amended to independent form and claims 2-28, 34-39 and 42 have been amended to depend (and/or have proper antecedent basis) from claim 30 rather than claim 1. Support of these amendments can be found throughout the specification as filed, for example on page 9, lines 3-5. Claims 30 and 52 have been amended to incorporate the definition of "non-canonical zinc finger" from the specification. *See*, for example, page 18, line 19 through page 20, line 31. Claims 37 and 47 have been amended to include a maize C1 activation domain, as described for example on page 52, line 15 and page 23, lines 21-22. Claim 43 has been amended to include the gamma-tocopherol methyltransferase (GMT) gene (see, *e.g.*, Example 7). Claim 29 has been cancelled, without prejudice or disclaimer. Accordingly, claims 1-28 and 30-52 are presently pending.

RESTRICTION

The Examiner has required restriction to one of the following allegedly distinct groups of claims:

- Group I (claims 1-29, 33-38 and 52), drawn to a zinc finger protein;
- Group II (claims 30-32 and 39-41), drawn to a nucleic acid; and
- Group III (claims 42-51), drawn to a method of modulating gene expression;

Applicants traverse the Restriction Requirement.

Applicants submit that the Office has not met its burden in establishing the two criteria that must be met in order for restriction requirement to be proper under M.P.E.P. § 803, namely (1) the inventions must be independent or [*sic*] distinct as claimed¹; and, in addition, (2) there must be a serious burden on the Examiner if restriction is not required.

In support of restriction as between Groups I and II, the Examiner asserts that the claimed proteins and polynucleotides are "chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other groups (each of which can

¹ Applicants note that the statutory criteria for restriction are **both** independence and distinctness. 35 U.S.C. § 121; 37 C.F.R. § 1.141(a); 37 C.F.R. § 1.142(a)

be isolated from cells or organisms, made synthetically, and/or are self-replicating without the need for the isolated products of the other groups." (Restriction Requirement, pages 2-3). Furthermore, with respect to Groups I and III, the Restriction Requirement asserts that the "product as claimed can be used in a materially different process, to isolate DNA or label DNA." (Restriction Requirement, page 3). Finally, with respect to Groups II and III, the Restriction Requirement states that the Groups are unrelated because "the product of Group II is not used in or made by the methods of Group III." (Restriction Requirement, page 3).

Applicants submit that the Examiner has not demonstrated that the claims of Groups I and II are distinct from each other. As a threshold matter, Applicants note that neither proteins nor polynucleotides are capable of self-replication. In addition, being non-naturally-occurring molecules, neither the claimed proteins nor the claimed polynucleotides can be purified from cells or organisms. Finally, the claimed proteins are too long (>60 amino acids) to be easily synthesized and purified using standard peptide synthesis techniques.

With respect to Restriction between Groups I and III, the Office has asserted that the claimed non-naturally-occurring proteins can be used to isolate DNA or label DNA. Applicants are not aware of any methods in which the claimed proteins can be used to isolate or label DNA, and request that the Office provide specific, substantial and credible examples of the asserted methods for isolation and labeling of DNA, if the Restriction Requirement is maintained.

With respect to Restriction between Groups II and III, the Office has asserted that the polynucleotides of Group II are not used in the methods of Group III. In response, Applicants note that the claims, as amended, recite polynucleotides (Group II) which **are** used in the claimed methods of Group III. Accordingly, the Office's assertion no longer applies, and restriction between Groups II and III should be withdrawn.

Accordingly, Applicants submit that the justification for restriction between Groups I and II is not based on credible utilities for the claimed proteins and nucleic acids. If the Restriction Requirement is maintained, Applicants request that the Office identify how the claimed isolated molecules can be self-replicating and identify a synthetic peptide synthesis technique capable of synthesis of a protein comprising at least two zinc finger DNA-binding domains. Applicants additionally request that the Office identify how to label or isolate DNA with the proteins.

Applicants also traverse on the grounds that it would not be unduly burdensome to search the allegedly distinct inventions together. In fact, a search for any references relevant to one Group will reveal art relevant to the others. It would, therefore, not be burdensome (and even save the Office time and resources) to examine the claims together.

Moreover, there is nothing in the Restriction Requirement to support the contention that it would impart a serious burden to examine all the claims together. In fact, examination of these claims in one application would not place an undue burden on the Examiner, but would actually save the Examiner time. In light of the Office's concerns about increasing numbers of applications, examination of the pending claims in a single application would also save Patent Office resources.

Applicants expressly reverse their right to rejoinder of process claims 42-51 (as amended herein). Furthermore, Applicants expressly reserve their right under 35 USC §121 to file one or more divisional applications directed to the nonelected subject matter during the pendency of this application. Furthermore, should the Examiner instead choose to make this restriction requirement FINAL, Applicants reserve their right, pursuant to 37 C.F.R. §§ 1.144 and 1.181, to petition this requirement at any time during the pendency of this application, prior to appeal.

Finally, in light of the long-established statutory criteria for restriction, Applicants note that the Office has neither asserted, nor provided any evidence supporting, independence of the three Groups.

In conclusion, and solely for the purposes of compliance with 37 C.F.R. § 1.143, Applicants provisionally elect Group II, claims 30-32, 39-41 and amended claims 2-28 and 34-38, **with traverse**.

ELECTION OF SPECIES

The Examiner has also required election of a single disclosed species among the following:

1. target sequence type;
2. specific zinc finger component;
3. where target is located;
4. functional domain type; and
5. specific target site in a gene.

As a threshold matter, Applicants note that the election of species requirement is unclear. The Examiner has not indicated what the distinct species are considered to be and on what basis they are distinct. In particular, the election of species requirement fails to adequately set forth and define the allegedly distinct species. For example, no species are indicated in the allegedly generic claims of any of the groups. Particularly for group 5, it is impossible for Applicants to select from unidentified species. Therefore, Applicants request that the species election requirement, if maintained, be redefined and clarified.

Applicants traverse on the grounds that the election of species requirement is not adequately set forth. Applicants also traverse on the grounds that it would not be unduly burdensome to search the entire scope of the claimed subject matter. In fact, a search for any polynucleotide encoding any non-canonical zinc fingers that recognizes any target sequence and/or further encodes any functional domain and modulates expression in any cell type would necessarily reveal relevant art to each of the allegedly distinct species. It would, therefore, not be burdensome (and even save the Office time and resources) to examine the claim as a whole.

Applicants also note that, contrary to the statement on page 4 of the Office Action, 35 U.S.C. § 121 **does not** require provisional species election; it requires provisional election in response to a Restriction Requirement.

Nonetheless, in a sincere effort to advance prosecution, Applicants elect, **with traverse**, for groups 1-4 set forth above:

1. DNA target sequence (which reads on claims 1, 2, 4, 6-28 and 30-52);
2. a zinc finger component comprising X₃-Cys-X_{2,4}-Cys-X₁₂-His-X_{1,7}-Z-X₄ (which reads on claims 1-6, 10, 22-28 and 30-52);
3. target located in plant cell (which reads on claims 1-22, 25-28, 30-49 and 52); and
4. an activation domain, particularly maize C1, (which reads on claims 1-28, 30-33, 36, 37, 39-43, 46, 47 and 49-52).

As noted above, Applicants request clarification regarding the species allegedly belonging to group 5.

Finally, it is to be understood that the election of species is for the purposes of preliminary search and examination only, and that upon allowance of a generic claim,

applicants will be entitled to consideration of claims to the additional species.

Applicants expressly reserve their right under 35 USC §121 to file one or more divisional applications directed to any nonelected subject matter during the pendency of this application.

Respectfully submitted,

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